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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,532	ERBACHER ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 9/29/2006 is acknowledged. After entry of the amendment, claims 18-46 are pending and under examination.

Claim Objections

Claim 37 is objected to because of the following informalities: "growth factor" should be "a growth factor". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-20 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Milieva et al (J Appl Toxicol., (1995)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sykora et al (Folia Microbiol., (1991)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by GB1277086.

The above rejections are maintained for reasons made of record in the previous Office Action and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 9/29/2006 have been fully considered but they are not persuasive. Applicants arguments regarding the above rejections are essentially the same, hence the are addressed together. Applicants essentially assert that the above prior art documents do not teach the use of the claimed compositions including an exogenous compound in transfection or delivery methods of the exogenous compound. However, the instant claims are not process claims, but rather product claims, and thus are not limited by any intended use limitations. See MPEP 2111.02, which states:

> *"If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." ;*
>
> *"where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation", and ;*
>
> *"If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim."*

Regarding the third and last quote above, if applicants believe the prior art compositions are not capable of performing the claimed intended use, then applicants are encouraged to provide evidence or scientific reasoning as to why the prior art compounds are not so capable.

Furthermore, all of the above references teach exogenous compounds used in conjunction with the disclosed compounds (as recited in claim 18). Milieva et al teach the use of N,N,N',N'-tetramethyl-N,N'-di(8,15-dicloropentadeca-5,10-dien)ethylenediamine methylsulphate in Kreb's solution, which contains glucose (a carbohydrate) and sodium chloride (see page 219, second

column). Sykora et al teach the use of BDHD in Luria Broth, or LB medium. Luria broth comprises peptides and sodium chloride, both of which are within the scope of exogenous compounds recited in claim 18. See the Conda catalog entry (2006) and Wikipedia entry (2006) for the components of Luria Broth. Sodium chloride is considered a pharmaceutical compound because it is found in Ringers's solution, itself considered a pharmaceutical that is used intravenously to maintain an isotonic balance with blood (see Wikipedia entry for Lactated Ringer's solution, 2006).

The '086 document discloses the use of hexamethylenebis-(n-decyldimethyl-ammonium)dibromide, hexamethylenebis-(n-dodecyldimethyl-ammonium)dibromide, hexamethylenebis-(n-octyldimethyl-ammonium)dibromide, hexamethylenebis-(n-nonyldimethyl-ammonium)dibromide, and hexamethylenebis-(n-undecyldimethyl-ammonium)dibromide. These compounds may be used in conjunction with a surface active agent, such as sodium lauryl sulfate (page 2, lines 50-61). Sodium lauryl sulfate is considered a pharmaceutical compound because of its use in shampoos, toothpastes and pharmaceutical preparations (see USDA Technical Evaluation Report, 2/10/2006, lines 62-63 and 295-297).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-26, 28-38, and 40-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, and 11-46 of U.S. Patent No. 6,733,777 as follows: instant claims 18-20 over patent claims 1-8, respectively, instant claims 21-26 over patent claims 17-22, respectively, and instant claims 28-32 over patent claims 24-28, respectively, instant claim 33 over patent claims 5, 29, and 30, instant claims 34-35 over patent claims 32-35, instant claims 36-38 and 40-44 over patent claims 6, 7, 16 and 36-46. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods and kit of the patent claims use the compounds of the instant claims. Thus, in the absence of restriction requirement, the instant compounds are obvious in view of the patent methods. **This rejection is maintained for reasons made of record in the previous Office Action and for reasons set forth below. Claims 33-46 have been added to this rejection due to amendment of the claims.**

Response to Arguments

Applicant's arguments filed 9/29/2006 have been fully considered but they are not persuasive. Applicants essentially assert that amendments to the instant claims obviate this rejection. Applicants point to no specific limitations in the instant claims that define over the

claims of the '777 patent, which encompass the claimed subject matter for reasons set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections necessitated by amendment of the claims.**

Claim 33 recites the limitation "lipid-like molecule" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Furthermore, it cannot be determined how close to the original lipid a "lipid-like" molecule must be in order to fall within the scope of the claimed subject matter. Thus, the skilled artisan could not determine infringement of the claim, rendering the metes and bounds of the claimed subject matter unclear.

Claims 45 and 46 recite the limitation "the DNA/cationic cytofectin (w/w) ratio" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39, 45, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 39 recites co-lipid molecules linked to the exogenous compound of claim 18. Claims 45 and 46 recite particular DNA/cationic cytofectin ratios. Applicants point to page 9 of the disclosure for support of claim 39 and page 8 for claims 45 and 46. A review of the disclosure as filed, including pages 8 and 9, does not reveal support for linking a cell targeting co-lipid to the exogenous compound. Furthermore, there is no disclosure of any DNA/cationic cytofectin ratios, only DNA/liposome or DNA /lipid ratios (page 8 of the specification). Thus, the claims contain impermissible New Matter. **This new rejection was necessitated by amendment of the claims.**

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER